IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

SANOFI-AVENTIS and)
SANOFI-AVENTIS U.S. LLC)
Plaintiffs,) 1:07CV00086
v.)
)
SYNTHON HOLDING BV;)
SYNTHON BV;)
SYNTHON PHARMACEUTICALS, INC.;)
and SYNTHON LABORATORIES, INC.,)
Defendants.)

MEMORANDUM OPINION

Beaty, Chief Judge.

This case involves a patent infringement action brought by Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC ("Plaintiffs") against Defendants Synthon Holding BV, Synthon BV, Synthon Pharmaceuticals, Inc. and Synthon Laboratories, Inc. ("Defendants"). This matter is presently before the Court on Defendants' Motion to dismiss for improper venue under Federal Rule of Civil Procedure 12(b)(3) or, in the alternative, to transfer venue from the Middle District of North Carolina ("MDNC") to the Eastern District of North Carolina ("EDNC") pursuant to 28 U.S.C. § 1406(a) [Document #9]. For the reasons discussed below, the Court concludes that venue is not proper in this district, and that transfer to the EDNC is appropriate. Therefore, Defendants' Motion will be granted and this case will be transferred to the EDNC pursuant to

¹ Plaintiffs have also filed a Motion to File Sur-Reply [Document #28]. Although Sur-Replies are ordinarily not permitted under the Local Rules for this District, the Court has nevertheless considered Plaintiffs' proposed Sur-Reply, and this Memorandum Opinion represents the Court's full disposition of this matter in light of all of the arguments raised.

28 U.S.C. § 1406(a).

I. FACTUAL BACKGROUND

Plaintiff Sanofi-Aventis is a French corporation with its principal place of business in Paris, France. Plaintiff Sanofi-Aventis U.S. LLC, the U.S. subsidiary of Sanofi-Aventis, is a Delaware corporation having its principal place of business in Bridgewater, New Jersey. Sanofi-Aventis U.S. LLC ("Sanofi U.S.") holds the rights to U.S. Pat. No. 6,514,531 ("the '531 patent") relating to the medication zolpidem tartrate used in Sanofi U.S.'s product Ambien CR, which is used to treat insomnia. The '531 patent expires on July 16, 2021.

Defendant Synthon Laboratories, Inc. ("Synthon Labs") is a Virginia corporation with its principal place of business in Gainesville, Virginia. Synthon Labs filed an abbreviated new drug application ("ANDA") for a generic equivalent to Ambien CR on September 8, 2006, and it was accepted by the United States Food and Drug Administration ("FDA") for substantive review on November 28, 2006.² The ANDA contained a "Paragraph IV certification" which alleged that the '531 patent was invalid and not infringed.³ The ANDA was prepared primarily by Defendant Synthon BV, a Dutch corporation with its principal place of business in Nijmegen, Netherlands. The zolpidem tartrate extended release formulation that is the subject of the ANDA was developed in the Netherlands by Synthon BV and other third party contractors

² Synthon Labs also submitted a supplemental amendment to the ANDA on December 22, 2006 to include a 6.25mg extended release form of the tablet.

³ Plaintiffs have filed other patent infringement suits regarding the Ambien CR drug against other ANDA filers, but those actions are not part of the present suit.

located throughout Europe.

Defendant Synthon Pharmaceuticals, Inc. ("Synthon Pharms") is a North Carolina corporation with its principal place of business in Research Triangle Park, North Carolina. Jeffrey Troughton is a former employee of Synthon Pharms. Mr. Troughton assisted Synthon BV with the preparation of the initial zolpidem tartrate extended release ANDA. Mr. Troughton worked briefly at the Synthon BV facility in the Netherlands, as well as at the Synthon Pharms facility in Research Triangle Park, North Carolina. The ultimate parent company of Synthon Pharms, Synthon Labs, and Synthon BV is Defendant Synthon Holding BV, which is also a Dutch corporation with its principal place of business in the Netherlands.

This Court has previously addressed the issues of venue and personal jurisdiction with regard to Defendants Synthon Holding BV, Synthon BV, Synthon Labs, and Synthon Pharms. See Pfizer Inc. v. Synthon Holding, B.V., 386 F. Supp. 2d 666 (M.D.N.C. 2005). In Pfizer, this Court determined that the Defendants were subject to specific personal jurisdiction with respect to the filing of an unrelated ANDA that was at issue in that case, and the Court further determined that venue was proper in this district. Defendants now allege that several facts have changed since the Pfizer case, and that venue is no longer proper in this district, at least with respect to the present suit. In this regard, Defendants contend that although Defendant Synthon

⁴ The original ANDA, No. 78-735, was withdrawn approximately one month after submission on July 17, 2006. The currently pending ANDA, No. 78-483, was subsequently filed on September 8, 2006, as noted above. Mr. Troughton did not lend any further assistance to the preparation of the subsequent application.

Pharms previously operated at a facility in Chapel Hill, North Carolina in the MDNC, Synthon Pharms has since relocated its operations to a facility in Research Triangle Park, in Wake County, North Carolina in the EDNC. Defendants contend that this move occurred between December 2004 and February 2005, almost two years before the ANDA was filed and this action was commenced. Because Synthon Pharms' facility is now located in the EDNC, Defendants contend that with respect to the claims involved in this suit, venue is not proper in this district and that this case should therefore be dismissed, or in the alternative, transferred to the EDNC.

II. DISCUSSION

A. Determination of Venue

"When an objection to venue has been raised under Rule 12(b)(3), the burden lies with the plaintiff to establish that venue is proper in the judicial district in which the plaintiff has brought the action." Plant Genetic Sys. v. Ciba Seeds, 933 F. Supp. 519, 526 (M.D.N.C. 1996) (citing Bartholomew v. Virginia Chiropractors Ass'n., 612 F.2d 812, 817 (4th Cir. 1979)). Venue is proper in a patent infringement action "in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business." 28 U.S.C. § 1400(b) (2006). This creates two means of establishing venue in a patent case: (1) a defendant may reside in the district; or (2) a defendant may have committed acts of infringement in the district and have a regular and established place of business in the district.

In the present Motion, Defendants contend that venue is improper because Synthon Pharms does not reside in this district and does not have a regular and established place of

business in this district. In this regard, Defendants allege that Synthon Pharms is located in the EDNC and has insufficient contacts with the MDNC to support the finding that venue is proper in the MDNC. Defendants further contend that venue is improper as to the other Synthon Defendants as well. With regard to Synthon Labs, Defendants allege that Synthon Labs is incorporated and located in Virginia and that its only contacts with North Carolina are with the Synthon Pharms facility located in the EDNC.⁵ Defendants also contend that venue is not proper with respect to either Synthon Holding BV or Synthon BV, because although venue would be proper in any district if the foreign corporations were the only defendants, in cases such as the present case where there are both foreign and domestic defendants, venue for the entire action is only proper where it is proper as to the non-alien defendants. See Hall v. Tyco Int'l, Ltd., 223 F.R.D. 219, 231 (M.D.N.C. 2004). Because the venue determination as to Synthon Pharms is ultimately dispositive, the Court will focus its analysis on a determination of whether venue in the MDNC is proper as to Defendant Synthon Pharms, specifically whether Synthon Pharms (1) resides in this district, or (2) has committed an act of infringement in this district and has a regular and established place of business in this district.

1. Venue in Any District Where the Defendant "Resides"

⁵ This Court previously found that Synthon Labs was dominated and controlled by the other Synthon entities and was the alter ego of Synthon Pharms. See Pfizer Inc. v. Synthon Holding, B.V., 386 F. Supp. 2d 666, 670 (M.D.N.C. 2005). The Court need not revisit that issue in the present case, since, in any event, Synthon Labs' only connection to this district is through Synthon Pharms, and therefore venue would not be proper as to Synthon Labs if it is not proper as to Synthon Pharms.

As noted above, venue is proper in any district where the defendant resides. For purposes of venue, a corporation resides in "any district in which it is subject to personal jurisdiction at the time the action is commenced." 28 U.S.C. § 1391(c) (2006). Federal Circuit law, which applies in patent infringement cases, holds that the definition of "resides" found in § 1391(c) applies to venue in patent cases under § 1400(b). See VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574, 1583-84 (Fed. Cir. 1990). Under § 1391(c), if a defendant corporation is subject to personal jurisdiction in a state that has more than one judicial district, the corporation will reside in any district, in that state, in which it has contact sufficient to support a finding of personal jurisdiction. 28 U.S.C. § 1391(c) (2006). In determining whether there are sufficient contacts to support a finding of personal jurisdiction under this provision, each internal district within a multi-district state is to be treated as a separate state. See id.; VE Holding Corp., 917 F.2d at 1581 n.18 (citing H.R. Rep. No. 100-889 (1988), as reprinted in 1988 U.S.C.C.A.N. 5982, 6031). Therefore, to determine whether venue is proper, the Court must determine whether Synthon Pharms would be subject to personal jurisdiction in the MDNC if the district were treated as a separate state.

Personal jurisdiction may be either general or specific, depending on the nature of the defendant's contacts with the forum. <u>Cf. Aveka L.L.C. v. Mizuno Corp.</u>, 199 F. Supp. 2d 336, 339 (M.D.N.C. 2002). General personal jurisdiction arises from "continuous and systematic" contacts with the forum regardless of whether the contacts are related to the particular cause of action, and this standard has been interpreted to be rigorous. <u>See LSI Indus. v. Hubbell Lighting.</u>

Inc., 232 F.3d 1369, 1375 (Fed. Cir. 2000); see also Helicopteros Nacionales de Colombia, S. A. v. Hall, 466 U.S. 408, 104 S. Ct. 1868, 80 L. Ed. 2d 404 (1984); ALS Scan, Inc. v. Digital Serv. Consultants, Inc., 293 F.3d 707, 715 (4th Cir. 2002). In contrast, specific jurisdiction arises from contacts of the defendant with the forum that directly relate to the plaintiff's cause of action. Aveka, 199 F. Supp. 2d at 339. Courts looks at three factors in determining whether specific personal jurisdiction exists over a defendant: (1) whether the defendant purposefully directed its activities to the residents of the forum; (2) whether the claim arises out of or relates to the defendant's activities within the forum; and (3) whether assertion of personal jurisdiction is reasonable and fair. See Akro Corp. v. Luker, 45 F.3d 1541, 1545-46 (Fed. Cir. 1995).

In the present case, Plaintiffs raise five contentions in an attempt to establish that Synthon Pharms would be subject to personal jurisdiction in the MDNC for purposes of determining venue. First, Plaintiffs contend that the property on which Defendant Synthon Pharms' headquarters is located lies partially within the MDNC. Second, Plaintiffs contend that Synthon Pharms' principal mailing address, and that of its registered agent, is a post office box within the MDNC. Third, Plaintiffs contend that Synthon Pharms maintains leases on two properties in the MDNC. Fourth, Plaintiffs contend that Synthon Pharms pays property taxes in the MDNC for property located in this district. Finally, Plaintiffs contend that Synthon Pharms directly participated in the filing of the ANDA that is the subject of this litigation.

With respect to these contentions, Synthon Pharms has presented evidence to establish that its headquarters are located on a 10-acre piece of property in the EDNC, but that a few feet

of undeveloped, wooded land on the corner of the property crosses the county line into the MDNC. In addition, Synthon Pharms contends that all of their facilities, buildings, operations and employees are in the EDNC, and all real property taxes paid on the property are paid in Wake County, North Carolina in the EDNC. With respect to the post office box in the MDNC, Synthon Pharms notes that its street address is in the EDNC, but that its "P.O. Box" is simply located in a nearby Post Office that is in the MDNC because the Postal Service does not deliver mail directly to facilities in Research Triangle Park. Thus, Synthon Pharms contends that this situation is markedly different from a corporation that maintains a post office box in a state for purposes of doing business in the state, or a registered agent in a state for purposes of service of process. With respect to the leased property, Synthon Pharms acknowledges that it does maintain leases on two pieces of property in the MDNC that it previously used prior to its move to Research Triangle Park, but Synthon Pharms contends that it no longer uses those properties and that the properties have been or will be subleased to third parties. Similarly, Synthon Pharms notes that the property tax it pays is simply for furniture located in its former Chapel Hill facility that has been or will be subleased to a third party. Finally, with respect to the filing of the ANDA at issue in this case, Synthon Pharms notes that Jeffrey Troughton, a former employee of Synthon Pharms, participated at least to some extent in the preparation of this ANDA, but Mr. Troughton's work with respect to this filing was conducted either at Synthon BV's facility in the Netherlands or at the new Research Triangle Park facility of Synthon Pharms, located in the EDNC. In response, Plaintiffs do not contest Synthon Pharms'

factual assertions as to these matters, and Plaintiffs instead contend that these contacts are nevertheless sufficient to establish that venue is proper as to Synthon Pharms in this action.

The Court has considered all of these contacts with the MDNC and finds that in this particular case, the contacts that Synthon Pharms has with the MDNC would not meet the 'continuous and systematic' standard to establish general personal jurisdiction over Defendant Synthon Pharms if this district were treated as a separate state for purposes of establishing venue in this case. Having reviewed the uncontested factual allegations on this issue, it is clear that Synthon Pharms relocated its operations from the MDNC to the EDNC long before the filing of the ANDA in this case and the commencement of this litigation. Notwithstanding the small corner of undeveloped land (representing only a few feet of a 10-acre plot) and the use of a P.O. Box at a nearby Post Office due to local Postal Service specifications, all of Synthon Pharms' operations, facilities and employees are in the EDNC, and Synthon Pharms does not maintain or operate any business in the MDNC. Likewise, although Synthon Pharms does still have unexpired leases on property in the MDNC that it no longer uses and that it intends to sublease, those leases do not establish "continuous and systematic" contact that would subject Synthon Pharms to general personal jurisdiction for any unrelated action if this district were treated as a separate state.

Moreover, the Court has considered Synthon Pharms' contacts with this district and concludes that none of the aforementioned contacts with the MDNC are related to the filing of the ANDA that is the subject of this action. To the extent that Synthon Pharms' former

employee, Mr. Troughton, was involved in the preparation and filing of the ANDA, all of Mr. Troughton's activities relating to the preparation of the ANDA were conducted within the EDNC or outside of the United States. In addition, to the extent that Synthon Pharms has some remaining contacts with the MDNC, such as its prior leases on property in this district and remaining personal property in this district, the present lawsuit does not arise out of those contacts and does not involve any type of dispute over Synthon Pharms' leases or personal property in this district. The Court therefore concludes that specific personal jurisdiction over Synthon Pharms would not lie in the MDNC in this action if the district were treated as a separate state for purposes of establishing venue.

Therefore, because neither general nor specific personal jurisdiction would exist over Defendant Synthon Pharms in the MDNC in this action if this district were treated as a separate state, Synthon Pharms cannot be determined to 'reside' in the MDNC within the meaning of § 1400(b) and venue cannot be established on this basis.⁶

⁶ The Court notes that this analysis is case-specific. <u>See LSI Industries Inc. v. Hubbell Lighting, Inc.</u>, 232 F.3d 1369, 1375 (Fed. Cir. 2000) (noting that there is no specific test for evaluating a defendant's contacts for personal jurisdiction purposes, and holding that "a court must look at the facts of each case to make such a determination"). Thus, in other cases, similar types of contacts would be considered to determine on a case-by-case basis whether the contacts would support the exercise of general or specific jurisdiction. Thus, the Court's analysis here is limited to the venue determination presently before it involving the particular circumstances of this case.

2. Venue Where Defendant Committed Acts of Infringement and Has a Regular and Established Place of Business

The second means for establishing venue is by a showing that the defendant has committed acts of infringement in this district and has a regular and established place of business in this district. See 28 U.S.C. \$1400(b) (2006). As detailed above, Defendant Synthon Pharms now maintains its established place of business in the EDNC at its Research Triangle Park facility. Synthon Pharms no longer maintains any places of business within the MDNC. Furthermore, with respect to the alleged acts of infringement, Mr. Troughton, who assisted in the preparation of the ANDA, worked from the Research Triangle Park facility in the EDNC, and in the Netherlands. As all preparation of the ANDA in this case happened outside of the MDNC, Synthon Pharms did not commit acts of infringement in this district. Therefore, venue is therefore not proper in the MDNC under this prong of § 1400(b).

B. Transfer of Plaintiffs' Claims for Patent Infringement Pursuant to 28 U.S.C. § 1406.

Having found that venue is not proper in this district as to Synthon Pharms, the Court must either dismiss the action or transfer it to a district in which the action could have been brought. See 28 U.S.C. § 1406(a). Defendants in this case request that the Court dismiss

⁷ The Court notes that under the holding of the Court of Appeals for the Federal Circuit in <u>VE Holding Corp. v. Johnson Gas Appliance Co.</u>, 917 F.2d 1574, 1580 n.17 (Fed. Cir. 1990), analysis of this second prong of § 1400(b) is not required for corporate defendants because it is already covered under the first prong for any place a corporate defendant "resides." However, to the extent Plaintiffs have raised this issue in their brief, the Court addresses this issue as set out above.

Plaintiffs' claims upon a finding that venue is improper in the MDNC. However, in the alternative, Defendants request that this case be transferred to the EDNC. In Response, Plaintiffs contend that if the Court finds that venue is improper in this district, the case should be transferred to the EDNC rather than dismissed. Thus, neither Plaintiffs nor Defendants ultimately oppose the transfer of this case to the EDNC. (See Memorandum in Support of Motion to Dismiss [Document #10]; Memorandum in Opposition to Motion to Dismiss [Document #23].) Defendants assert that the EDNC is a district in which the case could have been brought and is a proper forum, and Defendants note that for purposes of this action they do not contest jurisdiction in that district. Thus, all of the Defendants consent to venue in the EDNC, and the Court finds that it is in the interests of justice to transfer the case rather than dismiss it. Therefore, this case will be transferred to the EDNC pursuant to 28 U.S.C. § 1406(a).

III. CONCLUSION

For the reasons discussed above, the Court concludes that venue is not proper in this district under 28 U.S.C. § 1400(b). Accordingly, Defendants' Motion to Dismiss, or in the Alternative, to Transfer Venue [Document #9] is GRANTED and this action will be TRANSFERRED to the United States District Court for the Eastern District of North Carolina. An Order in accordance with this Memorandum Opinion shall be entered contemporaneously herewith.

This, the 20th day of March, 2008.

United States District Court Judge